UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,759	03/03/2006	Mingdong Zhou	11748-006-999	7322

20583 7590 06/08/2010

JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER	
GODDARD, LAURA B	

ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
06/08/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/516,759	ZHOU, MINGDONG	
	Examiner	Art Unit	
	LAURA B. GODDARD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,6,9-14,44 and 45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,6,9-14,44 and 45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/5/10*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Amendment filed March 5, 2010 in response to the Office Action of December 8, 2009, is acknowledged and has been entered. Claims 4, 6, 9-14, 44, and 45 are pending and being examined. Claim 4 is amended.

New Rejection

(based on new considerations)

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 4, 6, 9-14, 44, and 45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for treating a neoplasm in a mammal, wherein the neoplasm expresses ErbB-3, comprising the administering to the mammal the claimed ErbB-3 extracellular domain proteins, does not reasonably provide enablement for said method for *preventing or delaying* a neoplasm or treating any *neoplasm that does not express ErbB-3*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some

experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The specification discloses proteins that comprise ErbB-3 extracellular domain sequences including SEQ ID NO:2 ("B3"), SEQ ID NO:3 ("DE3-1"), SEQ ID NO:14 ("ErbB3-f12"), and SEQ ID NO:16 ("ErbB3-f78") (Figures 5, 11, 23, and 25). The specification discloses that ErbB-3 proteins can elicit an immune response to a neoplasm to be treated (p. 12). The specification contemplates administering ErbB-3 extracellular domain proteins SEQ ID NOs:2 and 3, as well as amino acid residues 24-81 of SEQ ID NO:14, and amino acid residues 2-139 of SEQ ID NO:16 (p. 13). The specification discloses administering SEQ ID NOs:2, 3, 14, and 16 (B3, DE3-1, ErbB3-f12, ErbB3-f78) to mice repeatedly and monitoring tumor development in mice, wherein Figure 15 indicates the tumor is breast cancer, which appears to be spontaneously

produce in FVB/N transgenic mice. The four ErbB3 proteins reduced tumor growth in mice (Tables 1-5).

One cannot extrapolate the disclosure of the specification to the scope of the claims because the specification does not provide guidance or examples for **preventing and delaying the growth of a neoplasm** as claimed and contemplated. No where does the specification provide a nexus between administration of the claimed ErbB3 extracellular proteins and the subsequent prevention or delay of neoplasm growth in a mammal. A search of relevant art does not reveal the prevention or delay of cancer growth comprising administering ErbB3 extracellular domain proteins. One of skill in the art could not reasonably extrapolate the examples in the specification to the predictable prevention and delay of cancer growth in mammals. The specification lacks the critical steps necessary in presenting some type of predictable response in a population of hosts deemed necessary to prevent cancer or delay cancer. Reasonable guidance with respect to preventing any cancer relies on quantitative analysis from defined populations which have been successfully pre-screened and are predisposed to particular types of cancer or have had cancer. The essential element towards the validation of a preventive therapeutic is the ability to test the drug on subjects monitored in advance of clinical cancer and link those results with subsequent histological confirmation of the presence or absence of disease. This irrefutable link between antecedent drug and subsequent knowledge of the prevention of the disease is the essence of a valid preventive agent. All of this underscores the criticality of providing

workable examples which are not disclosed in the specification for preventing and delaying neoplasms in mammals.

One cannot extrapolate the disclosure of the specification to the scope of the claims because the specification does not provide guidance or examples for treating **any neoplasms that do not express ErbB3**. The specification contemplates that the administration of ErbB3 extracellular domain proteins elicits an immune response in mammals against neoplasms, however those of skill in the art recognize that the immune response elicited against the ErbB3 extracellular domain proteins would be directed towards ErbB3 proteins specifically, and the immune response would not recognize the neoplasm if the neoplasm did not express ErbB3. The specification fails to exemplify and provide guidance for immune responses elicited against ErbB3 extracellular proteins predictably treating any neoplasm in a mammal, particularly neoplasms that do not express ErbB3. A high quantity of experimentation would be required to determine what neoplasms could be predictably treated in the absence of ErbB3 expression.

Therefore, in view the quantity of experimentation necessary, the breadth of the claims, lack of guidance in the specification, and the absence of working examples for prevention and delay of neoplasms in mammals, as well as the treatment of any neoplasm not expressing ErbB3, it would require undue experimentation for one skilled in the art to practice the invention as broadly claimed.

3. All other rejections recited in the Office Action mailed December 8, 2009 are hereby withdrawn in view of amendments.

4. **Conclusion:** No claim is allowed.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA B. GODDARD whose telephone number is (571)272-8788. The examiner can normally be reached on 7:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura B Goddard/
Primary Examiner, Art Unit 1642